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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/194,396	12/08/1998	JAN HOLGERSSON	45115-53906	3163

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MINTZ, LEVIN, COHN, FERRIS, GLOVSKY
AND POPEO, P.C.
ONE FINANCIAL CENTER
BOSTON, MA 02111

EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/194,396

Applicant(s)

HOLGERSSON ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-23, 29-31 and 34-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-23, 29-31 and 34-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 21-23, 29-31, and 34-36 are pending and being acted upon.
2. Applicant's amendments and remarks filed 10/18/04 are acknowledged. In view of the amendments, only the following rejections remain.
3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 29-31 and 34-36 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed, for the reasons of record as set forth in the paper mailed 11/12/02 and maintained in the paper mailed 4/16/04. This is a new matter rejection.

Specifically:

- B) "wherein the first polypeptide comprises the extracellular portion of a P-selectin glycoprotein ligand-1 ..." (Claim 29),
- D) "wherein the first polypeptide comprises a part of a P-selectin glycoprotein ligand-1 that mediates binding to selectin ..." (Claim 34).

Applicant's arguments, filed 10/18/04, have been fully considered but they are not persuasive.

Regarding B), Applicant again argues that the specification at page 8, lines 6-8, discloses "[t]he mucin/immunoglobulin expression plasmid was constructed by fusing the PCR-amplified cDNA of the extracellular part of PSGL-1 in frame via a BamHI site". Applicant also argues that "the ordinarily skilled artisan would clearly conclude that Applicants had possession of a fusion polypeptide comprising the extracellular part of PSGL-1, when in fact the claimed construct is the construct the Applicants exemplified in the specification".

Applicant is again advised that, disclosure of a single species comprises insufficient support for claims drawn to a genus. The specification teaches a construct of PSGL-1/mouse IgG_{2b}, but not the generic construct of the claim. Accordingly, Applicant did not have possession of the generic construct of the claim.

Regarding D), Applicant argues that that which is well known in the art need not be disclosed, that Seed et al. (1995) teaches the first 100 amino acids of PSGL-1 as being essential for P-selectin binding, and that Sako et al. (1995) teaches that the first 19 amino acids of PSGL-1 are capable of binding P-selectin.

Applicant is advised that under *Lockwood v. American Airlines Inc.* 107 F.3d 1565,41 USPQ2d 1961 (Fed. Cir. 1997), "Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed". A corollary to this finding would be that adequate written description does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Thus the "obvious" part of PSGL-1, i.e., the part that mediates binding to selectin, comprises the addition of new matter not originally disclosed in the specification as filed.

5. The following are new grounds for rejection necessitated by Applicant's submission of new references.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically, the phrase "a part of a P-selectin glycoprotein ligand-1 that mediates binding to selectin" is vague and indefinite as said "part" is not defined in the specification. Note that Applicant submitted two references with the amendment and remarks of 10/18/04. Seed et al. (1995) teaches the first 100 amino acids of PSGL-1 as being essential for P-selectin binding, whereas Sako et al. (1995) teaches that the first 19 amino acids of PSGL-1 are capable of binding P-selectin. Thus, in view of the newly submitted references, it is now unclear what part of PSGL-1 mediates

binding to selectin.

8. Claims 21-23 are allowed.

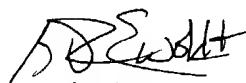
9. Applicant's amendment or action necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

11. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600


12/29/04
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER